

March 26, 2004  
Page 8

Serial No.: 09/927619  
Confirmation No.: 5353  
Applicant: PATEL et al.  
Atty. Ref.: 11836.0702.NPUS00

**REMARKS:**

**REMARKS REGARDING CLAIMS AMENDMENTS:**

Claims 1, 9, 32, and 35 have been amended as indicated above. Specifically, each claim has been amended to specify the nature of the surfactant.

Support for the above amendments to the claims can be found in the original specification as filed.

March 26, 2004

Page 9

Serial No.: 09/927619

Confirmation No.: 5353

Applicant: PATEL et al.

Atty. Ref.: 11836.0702.NPUS00

**IN RESPONSE TO THE OFFICE ACTION:****REJECTION UNDER 35 U.S.C. § 103:**

Claims 1, 4-9, 11, 13, 14, 17-22, 25-30, 32, and 35 have been rejected under 35 U.S.C. §103(a) as being unpatentable given WO 96/18383 (the WO '383 reference) in view of U.S. Patent No. 2,900,336 (the Brown reference) and U.S. Patent No. 5,189,012 (the Patel reference).

Applicants request that the Examiner reconsider and withdraw the above rejection of the claims in view of the following.

A determination under 35 U.S.C. §103 is whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. *In re Mayne*, 104 F.3d 1339, 1341, 41 U.S.P.Q. 2d 1451, 1453 (Fed. Cir. 1997). An obviousness determination is based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 U.S.P.Q. 459, 467 (1966), see also *Robotic Vision Sys., Inc. v. View Eng'g Inc.*, 189 F.3d 1370, 1376, 51 U.S.P.Q. 2d 1948, 1953 (Fed. Cir. 1999).

In line with this standard, case law provides that "the consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art." *In re Dow Chem.*, 837 F.2d 469, 473, 5 U.S.P.Q. 2d 1529, 1531 (Fed. Cir. 1988). The first requirement is that a showing of a suggestion, teaching, or motivation to combine the prior art references is an "essential evidentiary component of an obviousness holding." *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q. 2d 1225, 1232 (Fed. Cir. 1998). This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not "evidence." *In re Dembiczak*, 175 F.3d 994, 1000, 50 U.S.P.Q.2d 1614, 1617. The second requirement is that the ultimate determination of obviousness must be based on a reasonable expectation of success. *In*

March 26, 2004  
Page 10

Serial No.: 09/927619  
Confirmation No.: 5353  
Applicant: PATEL et al.  
Atty. Ref.: 11836.0702.NPUS00

*re O'Farrell*, 853 F.2d 894, 903-904, 7 U.S.P.Q. 2d 1673, 1681 (Fed. Cir. 1988); see also *In re Longi*, 759 F.2d 887, 897, 225 U.S.P.Q. 645, 651-52 (Fed. Cir. 1985). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *In re Fritch*, 972 F.2d 1260, 1265, 23 U.S.P.Q. 2d 1780, 1783-84 (Fed. Cir. 1992).

Applicant submits that nothing in the cited documents teaches or suggests the subject matter recited in independent claims 1, 9, 14, 22 and 32.

The WO '383 reference is generally directed to emulsions that contain a combination of emulsifiers having specific HLB values. (Page 3, lines 3-15). As is specifically taught, the selection of a polyglycerol fatty acid diester is limited to those compounds having an HLB value less than 5.0 and preferably from 4.0 to 4.9. The exemplary compounds, triglycerol dioleate and diglycerol dipalmitate generally meet this requirement. Further as is specifically taught, these compounds are used in combination with an emulsifier having an HLB value of about 8 to 10 as well as an emulsion stabilizer (i.e. magnesium sulfate).

As is shown on page 9 of the WO '383 reference, variation in the formulations taught result in unstable invert emulsions which in accordance with the teachings of the WO '383 reference are undesirable.

Applicant submits that nothing in the WO '383 teaches or suggests the modification needed to achieve the present invention. Specifically it should be noted that polyglyceryl-2 diisostearate has an HLB value of 5.5. This value of HLB is specifically given in the technical datasheet available from the source of this compound. (See attached) One of skill in the art would appreciate that this change in HLB value is attributable to the change in the structure of the molecule. Thus contrary to the Examiner's assertion, the proposed substitution would be counter to the teachings of the WO '383 reference because such substitutions would likely have the above noted effect. Applicant's assert that the basis for the Examiner's conclusion, while

March 26, 2004  
Page 11

Serial No.: 09/927619  
Confirmation No.: 5353  
Applicant: PATEL et al.  
Atty. Ref.: 11836.0702.NPUS00

reasonable on its face, is not supported by what one of skill in the art of surfactants and the formulation of drilling fluids would know.

Further to the extent that the remaining claims are dependent upon the above noted independent claims, under the provisions of 35 U.S.C. §112, 4<sup>th</sup> paragraph, all of the limitations of independent claim are expressly and inherently recited in the dependent claims. Applicants submit that the above arguments are equally applicable to the rejection of dependent claims 4-8, 17-22, and 25-29 and therefore nothing in the WO '383 reference in view of Brown and Patel teaches or suggests the subject matter of these claims


Given the above, Applicants request that the rejection of claims 1, 4-9, 11, 13, 14, 17-22, 25-30, 32, and 35 under 35 U.S.C. §103(a) be reconsidered and withdrawn and that the Examiner indicate the allowance of the claims in the next paper from the Office.

\*\*\*\*\*

The undersigned representative authorizes the Commissioner to charge any additional fees under 37 C.F.R. 1.16 or 1.17 that may be required, or credit any overpayment, to Deposit Account No. 13-3082, Order No. PA-00107US.

In order to facilitate the resolution of any issues or questions presented by this paper, the Examiner should directly contact the undersigned by phone to further the discussion.

Respectfully submitted,

  
Carter J. White  
Patent Attorney  
Reg. No. 41,374

Tel. 281 561 1450  
Fax. 281 561 1452  
Email: cjwhite@midf.com

Date: 3/26/04

**EMULPHARMA® PG20**

<b>Category</b>	Emulsifiers	
<b>Product code</b>	E0408A	
<b>Nature</b>	"PEG free" emulsifier suitable for the production of W/O emulsions by cold process	
<b>INCI name</b>	POLYGLYCERYL-2 DIISOSTEARATE.	
<b>Den. Iupac</b>	Isooctadecanoic acid, Di-ester with di-glycerol	
<b>CAS number</b>	67938-21-0	
<b>EINECS number</b>	2678216	
<b>Origin</b>	Vegetal / Synthetic	
<b>Specifications</b>	Form at 25°C	Viscous oily liquid
	Colour	Yellowish
	Odour	Slight
	Active substance, %	99.0 min.
	Water content, %	1.0 max.
	pH 5% water dispersion	5-7
	Hydrophilic-lipophilic balance	5.5
	Acid value	2.0 max.
	Saponification value	135 - 155
<b>Solubility</b>	EMULPHARMA® PG 20 is soluble in a number of organic solvents, including ethanol, isopropyl alcohol, n-propanol, acetone, ethyl acetate and dimethyl phthalate, and also in mineral and vegetal oils. The product is insoluble in water.	
<b>Preservatives</b>	Emulsion preparations must be preserved. Preservation must take further additives and production conditions into account.	
<b>Properties</b>	<p>Hydrophilic lipid with highly effective emulsifying properties for W/O systems.</p> <p>The major areas of application of EMULPHARMA® PG 20 include baby care products, water resistant sun protection products, nourishing creams, hand and body lotions, particularly for dry skin. Viscous oily liquid substance, suitable for the formulation of W/O emulsions "without PEG and mineral oil". Its liquid form allows cold processing.</p> <p>EMULPHARMA® PG 20 is particularly suitable for emulsifying W/O creams and lotions with water contents from 20 to 80% and an oily phase constituted by fatty oils of vegetable origin.</p> <p>With EMULPHARMA® PG 20, oils of different polarity range can be used to produce stable emulsions, using 2.5 - 4% of emulsifier, depending on the quantity and type of fatty phase used.</p> <p>It is odourless, non oxidizable and has excellent dermatological properties.</p> <p>The special water absorption properties make diglycerol ideal as a</p>	

moisturizing agent. For this reason EMULPHARMA® PG 20 is not only a W/O emulsifier that is free of ethylene oxide, but is also a special functional emulsifying system, able to create excellent skin feel properties.

Metal soaps can be added to provide consistency.

A magnesium or aluminium stearate (1:1 ratio) for example, provides improved gloss and better thermal stability and consistency.

Typical formulations for W/O creams can be found in the RES PHARMA formulary.

These applications demonstrate the versatility of EMULPHARMA® PG 20 in cool processing.

**Stability**

EMULPHARMA® PG 20 is not oxidizable, it is stable in neutral and slightly acid media, unstable in alkaline medium (hydrolysis of ester bond).

**Physiological properties**

Experiments with EMULPHARMA® PG 20 on human skin have shown that it has no irritant effect in the concentrations normally employed. Polyglycerol esters of edible fatty acids are licensed with the European Union as food additives. Polyglycerol esters can be used as emulsifiers and encapsulating materials for pharmaceutical active ingredients.

**Package**

Drums of 20 and 120 kg capacity.

**Notes**

The data submitted in this publication is based on our current knowledge and experience. It does not constitute a guarantee in the legal sense of the term and, in view of the multiple factors that may affect processing and application, does not relieve those to whom we supply our products from the responsibility of carrying out their own tests and experiments. Any relevant patent rights and existing legislation and regulations must be observed.